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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/508,765	05/13/2005	Stefan Golz	Le A 35 838 (004974.01073)	9673
22907 7590 02/11/2008 BANNER & WITCOFF, LTD. 1100 13th STREET, N.W. SUITE 1200 WASHINGTON, DC 20005-4051			EXAMINER LI, RUIXIANG	
			ART UNIT 1646	PAPER NUMBER
			MAIL DATE 02/11/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/508,765

Applicant(s)

GOLZ ET AL.

Examiner

Ruixiang Li

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2, 27, 28 and 32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2, 27, 28, and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application, Amendments, and/or Claims

The amendment filed on 11/30/2007 has been entered in full. Claims 2, 27, 28, and 32 are pending and under consideration.

Withdrawn Objections and/or Rejections

The rejection of claims 2, 3, and 26-31 under 35 U.S.C. 112, second paragraph because the steps of the methods do not necessarily achieve the goal set forth in the claim preamble is withdrawn in view of amended claim 2 canceled claims 3, 26, 29-31.

The objection to claims 2, 3, and 26 is withdrawn in view of amended claim 2 and canceled claims 3 and 26.

Claim Rejections under 35 U.S.C. §101

(i). 35 U.S.C. §101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

(ii). Claims 2, 27, 28, and 32 are rejected under 35 U.S.C. §101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. A specific and substantial utility is one that is particular to the subject matter claimed and that identifies a "real world" context of use for the claimed invention which does not require further research.

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Applicants argue that the specification asserts that the FRPL2 protein can be used in screening methods to identify potential therapeutic compounds for cardiovascular disorders and also provides evidence of the distribution of FRPL2 mRNA in cells and tissues of the cardiovascular systems. Applicants argue that in light of the disclosed unexpected high expression of FRPL2 in cardiovascular tissue and the knowledge in the art, the skilled artisan would readily perceive that FRPL2 modulation should be useful in the treatment of cardiovascular disorders.

Applicants' argument has been fully considered, but is not deemed to be persuasive for the following reasons. First, the assertion that the FRPL2 protein can be used in screening methods to identify potential therapeutic compounds for cardiovascular disorders does not represent a specific and substantial utility because such an assertion does not identify the specific cardiovascular disease that can be treated and what type of therapeutic compound, an agonist or antagonist of FRPL2, can be used for treating a cardiovascular disease. The specification at page 38 discloses that compounds that affect the activity of FRPL2 include both agonists and antagonists. The specification also lists cardiovascular disorders as one of many diseases that may be treated by therapeutic agents to be screened (page 4, last paragraph). Cardiovascular disorders further comprise many diseases with distinct pathological features (pages 55-57). Thus, the instant disclosure fails to disclose a specific disease to be treated with a compound screened by the instantly claimed method. Second, the prior art does not provide teachings on a causative link between the FRPL2 polypeptide and a specific

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cardiovascular disease. Clearly, further research would be required to determine whether there is a causative link between the FPRL2 polypeptide and a specific cardiovascular disease and whether an agonist or an antagonist of the FRPL2 screened by the instantly claimed method can be used to treat a cardiovascular disease. See *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966), noting that “a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.”

Claim Rejections under 35 USC § 112, 1st Paragraph

Claims 2, 27, 28, and 32 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections under 35 USC § 112, 2nd paragraph

(i). The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

(ii). Claims 2, 27, 28, and 32 are indefinite because they recite “FRPL2”. Such a term is determined arbitrarily without a definitive structure. Others in the field may isolate the same protein and give an entirely different name. Thus, reciting biochemical molecules by a particular name given to the polypeptide by various workers in the field fails to distinctly point out what the polypeptide is. Applicants should particularly point out and

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distinctly reciting the FRPL2 polypeptide by claiming characteristics associated with the polypeptide, such as a sequence identifier.

Applicants argue that independent claim 2 has been amended to recite the full name of the polypeptide and that the FRPL2 polypeptide was known in the prior art and the references were cited at page 4, lines 11-18 of the specification. Citing case law, Applicants further argue that a sequence identifier for a well-known protein should not be required.

Applicants' argument has been fully considered, but is not deemed to be persuasive because neither the specification (at page 4, lines 11-18) nor the prior art unambiguously defines the term as being a single well-known protein.

Claim Objections for Minor Informalities

Claim 27 is objected to because it depends from canceled claim 26. Appropriate correction is required.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you

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have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

Ruixiang Li

Ruixiang Li, Ph.D.
Primary Examiner
February 3, 2008

RUIXIANG LI, PH.D.
PRIMARY EXAMINER